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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/315,355 05/17/99 KEESEE

S MTP-023DV2

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HM12/0919

EXAMINER

BURKE, J

ART UNIT

PAPER NUMBER

1642

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DATE MAILED: 09/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/315,355

Applicant(s)
Keese et al

Examiner
Julie E. Burke (Reeves), Ph.D.

Group Art Unit
1642



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire zero month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 24-27 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 24-27 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented the instant claims in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct targets on cells to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species. Upon election, applicant is required to point out which nucelic acid encoding which protein reads upon the elected invention.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 24-27, in part, drawn to a method for detecting cervical cancer by detecting the presence of a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 69.4 kDa and an isoelectric point of about 5.8, classified in class 435, subclass 6. If group I is elected, the claims will be examined to the extent that they read upon a method of detecting a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 69.4 kDa and an isoelectric point of about 5.8.
- II. Claims 24-27, in part, drawn to a method for detecting cervical cancer by detecting the presence of a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 53.8 kDa and an isoelectric point of about 5.5, classified in class 435, subclass 6. If group II is elected, the claims will be

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examined to the extent that they read upon a method of detecting a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 53.8 kDa and an isoelectric point of about 5.5.

- III. Claims 24-27, in part, drawn to a method for detecting cervical cancer by detecting the presence of a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 47.9 kDa and an isoelectric point of about 5.6, classified in class 435, subclass 6. If group III is elected, the claims will be examined to the extent that they read upon a method of detecting a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 47.9 kDa and an isoelectric point of about 5.6.
- IV. Claims 24-27, in part, drawn to a method for detecting cervical cancer by detecting the presence of a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 46 kDa and an isoelectric point of about 5.1, classified in class 435, subclass 6. If group IV is elected, the claims will be examined to the extent that they read upon a method of detecting a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 46 kDa and an isoelectric point of about 5.1.
- V. Claims 24-27, in part, drawn to a method for detecting cervical cancer by detecting the presence of a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 44.9 kDa and an isoelectric point of about 6.6

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kDa, classified in class 435, subclass 6. If group V is elected, the claims will be examined to the extent that they read upon a method of detecting a nucleic acid which comprises a sequence encoding a protein having a molecular weight of about 44.9 kDa and an isoelectric point of about 6.6.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions of Groups I, II, III, IV and V represent separate and distinct methods which rely upon the detection of nucleic acid which encoded by materially different nucleic acids. The nucleic acids and the proteins thus encoded have different modes of operation, different functions and different effects. The methods of Groups I-V recite using structurally different nucleic acid molecules which encode structurally different proteins, as evidenced by the different molecular weights and isoelectric points. Because protein structure determines protein function, these structural differences indicate that the proteins would have different cellular locations, different stability and half-life and different cell cycle expression, thereby the methods are patentably distinct. The nucleic acid encoding these materially different proteins is also structurally distinct. In view of the fact that nucleic acid sequence determines nucleic acid transcription rates, stability of the mRNA intermediates and translation rates, all of which would affect the operation of the hybridization assay. The examination of all groups would require different searches in the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II, III, IV and V are patentably distinct.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Duncan Greenhalgh on 15 August 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, nee Reeves, Ph.D. whose telephone number is (703) 308-7553.



Julie E. Burke, nee Reeves, Ph.D.

September 15, 2000

JULIE BURKE
PRIMARY EXAMINER